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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,352

07/07/2003

Peter M. Bonutti

782-A03-003-1

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08/01/2006

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/614,352	Applicant(s) BONUTTI, PETER M.	
	Examiner Diane Yabut	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

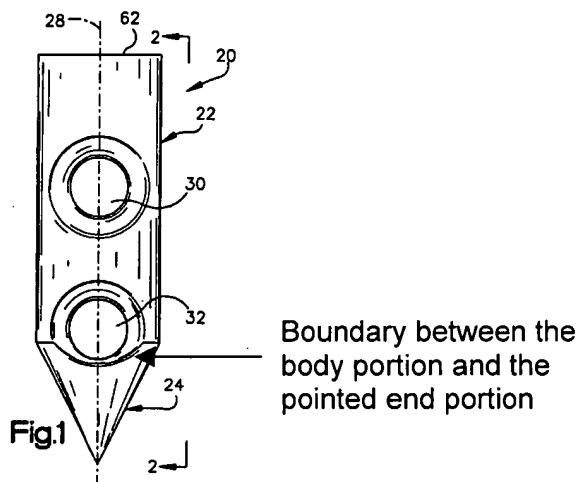
Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/7/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because Figure 1 does not show passage 32 formed partially in the body portion and partially in the pointed end portion since it appears that the pointed end portion begins below the boundary between the body portion and pointed portion and separate from passage 32. It must be clear as to where the boundary is between the body portion and the pointed portion.



Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes

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made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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3. Claims 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by **Adams** (U.S. Patent No. **6,099,552**).

Claims 9-11: Adams discloses a device comprising a cylindrical body **101** defining a longitudinal central axis and a pointed end portion **105** having a central axis which is coincident with the longitudinal central axis of the cylindrical body, a first opening defining a first passage through the cylindrical body in a direction transverse to the longitudinal central axis of the cylindrical body, and a second opening defining a second passage through the cylindrical body in a direction transverse to the longitudinal central axis of the cylindrical body, wherein the first passage and the second passage are substantially parallel (Figure 1). The device of Adams is capable of having the pointed end portion forming an opening in the body tissue in the patient's body when a force is applied against a trailing end of the cylindrical body in a direction extending along the longitudinal central axis of the cylindrical body.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bartlett** (U.S. Patent No. **5,540,718**) in view of **Ogiu et al.** (U.S. Patent No. **4,235,238**).

Claims 1-3 and 8: Bartlett discloses a device for securing a suture having a substantially cylindrical body portion defining a longitudinal central axis including a first end and a second end, wherein the second end is pointed and conical in shape and at least two bores may be used for threading of suture which define a passage (Figure 1A and col. 5, lines 34-37). Bartlett discloses the claimed device except for one of the passages being formed partially in the body portion and partially in the pointed end portion.

Ogiu et al. teaches a tissue-suturing apparatus with a passage used for threading suture that is formed partially in the body portion **1** and partially in the pointed end portion **3** (Figure 51). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Bartlett reference by having one of the passages being formed partially in the body portion and partially in the pointed end portion, since Applicant has not disclosed that having the passage being formed partially in the body portion and partially in the pointed end portion solves any stated problem or is for any particular purpose and it appears that the device of Bartlett would perform equally well with a passage formed partially in the body portion and partially at its pointed end portion.

6. Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**).

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Claims 12-21: Adams discloses the claimed device (see explanation for Claims 9-11 in paragraph 3) except for the cylindrical body being made of allogenic, autogenic, xenogenic, cortical bone, or a single piece of freeze dried bone, or made of a material selected from the group consisting of a metal, metal alloy, biodegradable material and bioerodible material, wherein the suture is secured relative to a body tissue being soft tissue or bone. It would have been obvious to one of ordinary skill in the art to use any of the above materials in either soft tissue or bone, since it was known in the art that these materials are used with suture devices with soft tissue or bone.

7. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**) in view of **Ogiu et al.** (U.S. Patent No. **4,235,238**).

Claims 22 and 23: Adams discloses the claimed device except for one of the passages being formed partially in the body portion and partially in the pointed end portion. See explanation for Claims 1-3 and 8 in paragraph 2 above.

8. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams** (U.S. Patent No. **6,099,552**) in view of **Bartlett** (U.S. Patent No. **5,540,718**) and **Bonutti et al.** (U.S. Patent No. **6,368,343**).

Claims 24 and 25: Adams discloses the claimed device except for a suture connected to the device under tension and extending through the first and second passages and a retainer connected to the suture for maintaining the tension in the suture and made of a material that becomes flowable when ultrasonic vibratory energy is applied.

Bartlett teaches a suture **64** connected to a device under tension and extending through the first and second passages, which is understood as the first and second passages not being separate passages, in order to be properly, fixedly threaded to the suture anchor (Figure 8, col. 6, lines 47-55). It would have been obvious to one of ordinary skill to provide a suture, as taught by Bartlett, to Adams in order for the suture to be fixed properly threaded through the device.

Bonutti et al. teaches a retainer connected to a suture for maintaining the tension in the suture and made of a material that becomes flowable when ultrasonic vibratory energy is applied so that when subject to pressure, there is insignificant deformation of the suture (col. 7, lines 8-17). It would have been obvious to one of ordinary skill to provide a retainer that becomes flowable when ultrasonic vibratory energy is applied, as taught by Bonutti et al., to Adams and Bartlett since it was known in the art that retainers maintain tension in sutures and that retainers made of flowable material is beneficial in preventing deformation of the suture.

Response to Arguments

Applicant's arguments with respect to the Bartlett reference are moot in view of the new rejections above, necessitated by Applicant's amendment.

Applicant argues that Bartlett does not disclose the use of two separate bores both for the passage of suture, and that the second hole that is only to be used by the insertion instrument. The examiner disagrees as discussed above. Applicant does not

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recite separate passages through the body portion, and the second hole is capable of being used with a suture, and therefore the Bartlett reference reads on this limitation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER